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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,455

12/14/2005

Silvia Gluck

13111-00027-US

3072

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,455	<b>Applicant(s)</b> GLUCK ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 18-22, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The amendment filed 12/10/08 is acknowledged.

Claims 1-7, 18-22 and 26-27 are being considered on the merits.

Claims 8-17 and 23-25 are withdrawn from consideration as directed to a non-elected invention.

It is noted that the microorganism(s) required to practice the claimed invention are currently available from DSMZ. It appears that the microorganism(s) should remain available to the public beyond the effective life of the patent. Any information to the contrary which comes to applicants' attention during the prosecution of this application must be inserted into the record or otherwise be brought to the attention of the Office by applicants.

**The complete name and address of the depository should be inserted in the specification.**

This application contains claims 8-17 and 23-25 drawn to an invention nonelected with traverse in the reply filed on 4/24/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 102-103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are/remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stetter *et al.*, (Arch Mikrobiol. 1973 Dec 31;94(3):221-47.) in light of DSMZ Catalogue.

The claims are directed to the microbiological isomerization of  $\alpha$ -hydroxy carboxylic acids using a lactate racemase, optionally using *Lactobacillus*.

Stetter *et al.* teach the microbiological isomerization of  $\alpha$ -hydroxy carboxylic acids using a lactate racemase produced by various *Lactobacillus* strains. See, e.g., Table 3, page 227 and Figure, page 237. That strain ATCC 15521 is the same as DSM 20017 is shown by DSMZ Catalogue. In addition, the reference discloses strain *L. delbrueckii* ATCC 9649 which is identical to DSM 20074 as shown by applicants in their proffer filed 12/10/08.

The lactate racemase produced by the strain of Stetter inherently has the property of isomerizing "at least one further (R)- or (S)- $\alpha$ - hydroxycarboxylic acid of the formula (I)" in addition to lactic acid.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Stetter discloses only the isomerization of lactic acid by lactate racemase and contends that Stetter does not teach that the compounds as recited in the claims could be the substrates of lactate racemase. However, all the claims require is that the lactate racemase be an enzyme which "isomerizes at least one further (R)- or (S)- $\alpha$ -hydroxycarboxylic acid of the formula (I)". It is submitted that the lactate racemase produced by the various strains of Stetter inherently have the property of isomerizing "at least one further (R)- or (S)- $\alpha$ - hydroxycarboxylic acid of the formula (I)" in addition to lactic acid, since they are the identical strains of applicant.

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 [24 USPQ2d 1321] (Fed. Cir. 1992). Thus, a prior art

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reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 [64 USPQ2d 1202] (Fed. Cir. 2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” *Id.* (quoting *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 [52 USPQ2d 1303] (Fed. Cir. 1999). Moreover, “[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; *see also Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 [67 USPQ2d 1664] (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

In the instant case the identical lactate racemases from the same microorganisms are each used in the same process of isomerizing an  $\alpha$ -hydroxycarboxylic acid of the formula (I).

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-7, 18-22 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stetter *et al.* taken with DSMZ Catalogue, Mori *et al.* and Seuffer-Wasserthal *et al.* (U.S. Patent No. 5,534,436).

The claims are directed to a process of treating an  $\alpha$ -hydroxycarboxylic acid with a lactate racemase and optionally isolating the mixture obtained and chemical or enzymatically treating it further.

Stetter *et al.* and discloses a process of treating an  $\alpha$ -hydroxycarboxylic acid with a lactate racemase using at least *Lactobacillus* strains DSM 20207 and DSM 20074 in the process, such as adequately demonstrated by DSMZ Catalogue, see, e.g., item 906, which is the Stetter *et al.* reference and applicant's proffer.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success of isomerizing various alpha-hydroxycarboxylic acids using microbial racemases, including the racemases obtained from the specific strains recited, including *L. paracasei* subsp. *paracasei* DSM 20207 and *L. sakei* 20074 known to possess suitable lactate racemase activity.

The reference differs from the invention as claimed in that further enzymatic or chemical modifications are not recited. However, Mori *et al.* adequately show that it was well known in

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the art at the time the claimed invention was made to modify compounds obtained in isomerization reaction or resolution reactions by converting a racemic compound into an optically active isomer. See, e.g., Examples. In addition, Seufer-Wasserthal *et al.* disclose the chemical or enzymatic enantioselective subsequent reaction that comprises esterification. See, e.g., col. 2, bridging paragraph between col. 2 and 3.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Stetter *et al.* and Mori *et al.* by using a variety of substrates and/or racemases and submitting the resultant product to further reactions such as esterification as suggested by the teachings of Mori *et al.* and Seufer-Wasserthal *et al.* for the expected benefit of obtaining pharmaceutically valuable optically active compounds that are important *per se* or which are useful intermediates to produce further optically active pharmaceuticals.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's argument that the Stetter reference does not teach the isomerization of an  $\alpha$ -hydroxycarboxylic is puzzling, since lactic acid is an  $\alpha$ -hydroxycarboxylic acid.

Applicant criticism of the secondary references Mori and Seufer-Wasserthal is noted. However, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

The examiner relies on Stetter *et al.* for the disclosure of isomerization of an  $\alpha$ -hydroxycarboxylic as claimed. The deficiencies argued by applicants in the secondary references fail to recognize that Stetter is relied on for the teachings. The secondary references are relied on

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only for their disclosure of knowledge in the art of the modification of compounds obtained in isomerization reaction or resolution reactions by converting a racemic compound into an optically active isomer and the disclosure of chemical or enzymatic enantioselective subsequent reaction that comprise esterification.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
Art Unit 1651